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Name: Sheryl L. Hutchings

Signature: Sheryl L. Hutchings

PATENT

Case No. 8627/1247 (PA-5573-PCT/US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re: patent application of)

Thomas A. Osborne)

Examiner: Michael T. Piery)

Serial No.: 10/581,330)

Group Art Unit: 1742)

Filed: March 7, 2007)

Confirmation No.: 3188)

INTRODUCER SHEATH AND)
METHOD FOR MAKING)

BRIEF OF APPELLANT

MAIL STOP APPEAL BRIEF-PATENTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

This appeal is taken from the decision of the Examiner mailed November 24, 2010, finally rejecting claims 1, 2, 4, 6-8, 10, and 21-33 of the present application. Appellant timely filed his Notice of Appeal to the final rejections on February 23, 2011.

I. REAL PARTY IN INTEREST

The real party in interest in this matter is the assignee of the application, Cook Incorporated, of Bloomington, IN.

II. RELATED APPEALS AND INTERFERENCES

There are no known prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-33 were presented for examination.

Of the above claims, claims 3, 5, 9, and 11-20 were canceled during prosecution.

Claims 1, 2, 4, 6-8, 10 and 21-33 stand finally rejected, and are appealed herein.

IV. STATUS OF AMENDMENTS

No amendments to the claims were presented subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present application discloses a method of manufacturing an introducer sheath. Introducer sheaths are typically used in the medical arts as a conduit for the introduction of a medical interventional device (e.g., angioplasty catheter, stent, etc.) into the vasculature. Introducer sheaths are typically thin-walled tubular devices that are fitted to an inner dilator for percutaneous placement over a wire guide.

Introducer sheaths are often formed as multi-layer constructions comprising an inner liner formed of a low friction, lubricious material such as

PTFE, an intermediate reinforcing layer consisting of a braid or a coil, and an outer layer formed of a thermoplastic compound, such as a polyamide, polyethylene, polyurethane, and the like. Introducer sheaths that incorporate a braid as the intermediate reinforcing layer generally do so to enhance the torqueability of the device. Braids are known to enhance torque control, which assists the physician when directing the introducer sheath into branch arteries and vessels. Introducer sheaths that utilize a coil as the intermediate reinforcing layer generally do so to enhance the kink resistance of the device. This allows the physician to manipulate the sheath external to the patient without kinking, and to conform to tortuous anatomy within the vasculature of the patient.

Multi-layer introducer sheaths such as those described above are generally constructed by placing the inner liner material over a mandrel. The braid or coil is then placed over the outer surface of the inner liner. The outer thermoplastic material is then placed over the braid or coil. A heat shrinkable sleeve is placed over the assembly, and the assembly is heated or baked in an oven. This causes the thermoplastic outer layer to melt and flow between the wires of the braid or coil, such that it bonds to the inner liner. When the assembly is cooled, the heat shrink sleeve is slit and peeled off the thermoplastic layer, and the mandrel is pulled out of the inner liner. The result is a thin-walled multi-layer tube suitable for use as a guide catheter or vascular sheath. One example of a coiled sheath formed in this manner is described in U.S. Patent No. 5,380,304.

Attempts have been made to construct introducer sheaths having both a braid and a wire coil as an intermediate layer, in order to achieve both enhanced torqueability and kink resistance in a single sheath. However, sheaths resulting from such combination exhibit shortcomings. For example, utilizing both a coil and a braid reinforcement in a "stacked" arrangement as the intermediate layer results in a structure that may be too thick-walled for some

proposed uses. In addition, the wire filaments of the respective coil and braid layered reinforcements are susceptible to interfering with each other. In this case, the resulting sheath may exhibit neither favorable torqueability nor kink resistance.

The present application includes two independent claims, namely claims 1 and 21. Claim 1 is directed to a method of manufacturing an introducer sheath. A coil 44 is positioned over a mandrel 40. Appl. p. 7, lines 25-30; p. 12, lines 24-28, Fig. 6(C). A first polymeric sleeve 34 is positioned over the coil and the mandrel. Appl. p. 8, lines 5-6, Fig. 6(D). The first polymeric sleeve comprises a first striped extrusion 36 arranged in a generally helical pattern along an outer surface of the first sleeve. Appl. p. 8, lines 24-28, Fig. 4. A second polymeric sleeve 30 is positioned over the first sleeve. Appl. p. 8, lines 6-8, Fig. 6(E). The second polymeric sleeve comprises a second striped extrusion 32 arranged in a generally helical pattern along the second sleeve. Appl. p. 8, lines 24-28. The second striped extrusion has a pitch extending in a generally opposite direction from a pitch of the first striped extrusion. Figs. 6(D), 6(E). A heat shrink tube 50 is positioned over an assembly comprising the mandrel, coil, and first and second sleeves. Fig. 6(F). The assembly is heated to a temperature sufficient to cause the heat shrink material to shrink, such that the first and second polymeric sleeves melt together to form a tubular polymeric sheath body enveloping said coil. Appl. p. 8, lines 11-23. The second striped extrusion is superposed over the first striped extrusion in the sheath body to define a generally braid-like configuration therein, wherein the braid-like configuration is disposed radially outwardly from the coil. Appl. p. 6, line 29 to p. 7, line 5.

Independent claim 21 is also directed to a method of manufacturing an introducer sheath. An inner liner 42 is positioned over a mandrel 40. Appl. p. 7, lines 26-28, Fig. 6(B). A coil 44 is positioned over the inner liner, the coil having a plurality of coil turns. Appl. p. 3, lines 28-29, Fig. 6(C). A first polymeric

sleeve 34 is positioned over the coil, the first polymeric sleeve comprising a first striped extrusion 36 arranged in a generally helical pattern along the first sleeve. Appl. p. 8, lines 24-28, Fig. 4. A second polymeric sleeve 30 is positioned over the first sleeve, the second polymeric sleeve comprising a second striped extrusion 32 arranged in a generally helical pattern along the second sleeve. Appl. p. 8, lines 6-8. The second striped extrusion has a pitch generally opposite a pitch of the first striped extrusion. Figs. 6(D), 6(E). The second sleeve is aligned over the first sleeve such that upon a melting of the sleeves the second striped extrusion is superposed over the first striped extrusion and a generally braid-like configuration is defined thereby. Appl. p. 6, line 29 to page 7, line 5. A heat shrink material 50 is positioned over an assembly comprising the mandrel, inner liner, coil, and first and second sleeves. The assembly is heated to a temperature sufficient to cause the heat shrink material to shrink. Appl. page 8, lines 11-23. The heating further causes the first and second sleeves to melt together to form an outer tubular layer and to define the generally braid-like configuration therein, wherein the heat shrink material causes the outer tubular layer to bond to the inner liner through the coil turns. Appl. p. 3, lines 28-29; page 8, lines 11-30.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1, 2, 4, 6-8, 10, 21-30 and 33 were rejected under 35 USC 103(a) as being unpatentable over Hoste (US 6,508,806)("Hoste") in view of van Muiden (EP 0662385)("van Muiden").

2. Claims 31 and 32 were rejected under 35 USC 103(a) as being unpatentable over Hoste in view of van Muiden, as applied to claims 21 and 27, and further in view of Garabedian et al. (US 6,171,295)("Garabedian").

VII. ARGUMENT

ISSUE 1.

Are claims 1, 2, 4, 6-8, 10, 21-30 and 33 unpatentable under 35 USC 103(a) over Hoste in view of van Muiden?

Claims 1, 2, 4, 6-8, 10 and 33:

The claims of the present application address the problem of providing a sheath having both torqueability and kink resistance, while at the same time having a minimal wall thickness. The method of manufacturing the sheath as described in the present claims is neither taught nor suggested by the art of record.

According to the method of claim 1, a coil is positioned over a mandrel, and a first polymeric sleeve is positioned over the coil and the mandrel. The first polymeric sleeve comprises a first striped extrusion arranged in a generally helical pattern along an outer surface of the first sleeve. A second polymeric sleeve is positioned over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve. The second striped extrusion has a pitch extending in a generally opposite direction from the pitch of the first striped extrusion. The assembly is positioned in a heat shrink tube, and heated to a temperature sufficient to cause the heat shrink tube to shrink, whereby the first and second polymeric sleeves melt together to form a tubular polymer sheath body enveloping the coil. The second striped extrusion is superposed over the first striped extrusion in the sheath body to define a generally braid-like configuration disposed radially outwardly from the coil.

As the first and second polymeric sleeves melt together, the striped extrusions having the opposing pitches flow together in the heat shrink tube to define the generally braid-like configuration as described. At the same time, the melted polymeric sleeve envelopes the coil. As a result, a relatively thin-

walled sheath is formed that provides both kink resistance (from the coil) and torqueability (from the braid-like configuration) to the sheath.

Hoste teaches a method of making an introducer sheath wherein a coil is positioned over a braid (or vice versa) to form a dual layer reinforced wall, which reinforced wall construction is stabilized in a polymeric matrix. However, Hoste does not teach positioning two sleeves with striped extrusions on a coil, and heating the resulting assembly, as claimed herein. Van Muiden was cited for teaching a method wherein a second sleeve with a striped helical pattern was positioned over a first sleeve to define a braid-like configuration.

Hoste teaches a catheter construction for use, e.g., in guiding catheters or in angiography catheters. Hoste specifically points out that it is an important feature of such catheters to have as thin a catheter wall as possible. Notwithstanding this expressed desire for a thin-walled catheter, Hoste designed his catheter to include a stacking arrangement wherein the first reinforcing member is stacked on the second reinforcing member. This construction necessarily increases the wall thickness, or radial extension, of the catheter when compared to a catheter having a single reinforcing member, since it is necessary to provide sufficient space (i.e., thickness) along the catheter wall for each of the two reinforcing members. Thus, although Hoste recognized the problem of excessive wall thickness, and the desirability of providing as thin a catheter wall as possible, his solution does not alleviate this problem of excessive wall thickness. In fact, his design adds additional structure (e.g., the second reinforcing member), and therefore additional thickness, to the wall when compared to an otherwise similar sheath having a single reinforcing member.

As stated by the Examiner, van Muiden teaches that it is known to form a reinforcing member by positioning a first polymeric sleeve with a striped helical pattern over a mandrel and positioning a second polymeric sleeve with a striped helical pattern over the first sleeve to define a substitute for a braid. As

shown in Fig. 4, an extrusion profile 30 is made up of two coaxial layers 31, 32, each having a number of extruded helically shaped bands of material. The bands of material 33 in the outermost layer 31 are running in the opposite direction as the bands of material 34 in the innermost layer 32. Upon extrusion, a bond is said to be formed between the two layers with the helically shaped layers of material formed inside.

However, as shown in Fig. 4 of van Muiden, the integrity of the separate layers 31, 32 is maintained. Thus, even though van Muiden recognizes the trend toward ever thinner catheters (Col. 1, line 17), he maintains two separate layers in order to provide his substitute for a conventional braided reinforcement. In fact, according to van Muiden, the combination of the two layers is necessary to provide the effect of only a single reinforcing element, e.g., the braid. No teaching or suggestion of a heat shrink step to radially compress, or shrink, the layers is provided. Thus, even though van Muiden recognized the desirability of providing a thin-walled catheter, he designed an arrangement wherein the integrity of two extruded "stacked" layers is maintained. The layers do not undergo a heat shrink to compress the layers that define the braid, in order to provide a thin-walled arrangement of the type desired in the art. In addition to the foregoing, it is significant that van Muiden provides no teaching or suggestion of a manner by which his structure can be combined with a coiled reinforcement. Nor is it apparent how this could be done without adding still more thickness to the wall of the catheter.

Like van Muiden, Hoste also recognized the desirability of reducing the wall thickness of the catheter (see, e.g., Col. 2, lines 29-32; Col. 3, lines 54-57). Nonetheless, he also maintains discrete, radially-stacked, reinforcing members in his catheter. Hoste provides no teaching or suggestion of achieving a braid function by heat shrinking two layers together. Rather, he teaches multiple discrete reinforcement layers sandwiched between an inner liner and an outer

jacket. This is best shown in Fig. 2 of Hoste, in which the four discrete layers are shown.

Thus, it is clear that the cited references, either individually or in combination, fail to teach or suggest a sheath capable of both enhanced torqueability and kink resistance, and at the same time, maintaining a thin sheath wall.

Unlike either of the cited references, the method of claim 1 addresses the problem of providing both kink resistance and torqueability in a thin-walled sheath by positioning dual polymeric sleeves over a mandrel in the manner described above. A separate coil reinforcement is provided, and the sleeves are melted together in a manner such that the resulting sheath outer layer includes the superposed striped extrusions that define the braided reinforcement. Thus, separate defined sleeves for providing these features are not required, nor is a discrete outer layer required. Neither reference teaches or suggests the elegant arrangement as claimed herein.

Although the Examiner contends that the claim can be derived by combining the subject matter of Hoste and van Muiden, the appellant respectfully disagrees. The shrink jacket process of Hoste necessitates the presence of two reinforcing members radially arranged along the wall thickness. Even as the heat shrink is carried out, the presence of the reinforcing members occupy space in the wall. The Examiner acknowledges this deficiency in Hoste with his statement that "The examiner interprets that the shrink jacket process of Hoste when modified by van Muiden would form an assembly where the sleeves are melted together to obtain a braid configuration." OA, page 3.

Appellant respectfully states that this rationale is untenable for multiple reasons. It is clear that van Muiden does not teach or suggest that a reduction in wall thickness results from his dual extrusion layers. This is evident in his Fig. 4. Thus, the step of forming a sheath having the generally braid-like configuration by melting together two sleeves in a heat shrink tube is *not* taught

or suggested in van Muiden (which utilizes an extrusion process). Even when Hoste's process is modified by incorporating the teachings of van Muiden, those teachings do not support melting the layers of van Muiden together to form a braid-like configuration. Clearly, neither reference gives any indication that a *heat shrink* step can, or even should, be carried out to achieve a braid function. In the absence of a teaching or suggestion in either reference to form a braid-like configuration *by melting together two sleeves having opposing striped extrusions to form a single layer* as described, it is clear that this feature is a product of inventive contribution.

Appellant respectfully submits that the test for obviousness is not whether the features of a reference may be bodily incorporated into the structure of another reference, but rather, what the combined teachings of the references would have suggested to those of ordinary skill in the art. "Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The Court noted that "[t]o facilitate review, this analysis should be made explicit." *Id.* at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obvious grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."))

Thus, to support an obviousness rejection under Section 103, the Examiner should explicitly identify a reason that would have prompted one of ordinary skill in the relevant field to improve the known device in the same manner as the claimed invention. *Id.* Appellant respectfully submits that the present rejections lack sufficient articulated reasoning with rational underpinnings to support the rejections. Indeed, notwithstanding the expressed

desirability of providing a sheath having a minimal wall thickness, the cited references direct the artisan in a different, and less desirable, direction from that recited in the subject claims.

"A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *See, KSR*, 550 U.S. at 418. "A factfinder should be aware...of the distortion caused by hindsight bias and must be cautious of arguments relying on *ex post* reasoning." *Id.*, at 421. In addition to the foregoing, *KSR* further states that "[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *Id.* (citing *U.S. v. Adams*, 383 U.S. 39, 51-52 (1966)). Clearly, as detailed in the discussion above, the references do not teach the elegant claim feature of providing the braid feature as a structural result of the heat shrink step, but rather, lead the artisan in a different direction. Such teaching away provides additional evidence of the nonobvious of the present claims in view of the cited combination of references. This is particularly significant when, as here, the minimized wall thickness of the sheath that is achievable by the claimed method was also considered a highly desirable feature by both Hoste and van Muiden.

As stated, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. In making a *prima facie* determination of obviousness, the Examiner should identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known. *Id.*

Appellant respectfully submits that a *prima facie* case of obviousness of claim 1 in view of the cited combination of references has not been set forth by

the Examiner. Each of the references recognizes the problems of excessive wall thickness in a sheath, and accordingly, the desirability of providing a thin-walled sheath. In spite of this recognition, the references fail to teach or suggest the solution to the problem arrived at by the present claims. Hoste maintains a structure having discrete layers 17, 18, 19 as described. Van Muiden's combination of the dual extruded sleeves does not advance the desire of maintaining a low wall thickness in the elegant manner as claimed herein. Appellant submits that no articulated reasoning with rational underpinning has been provided to support the obviousness finding, as required, and that it is only after the benefit of Appellant's disclosure is gained, that the features of the invention may appear to be obvious.

For at least the foregoing reasons, Appellant submits that claim 1 is not obvious in view of the cited combination of references. Claims 2, 4, 6-8, 10, and 33 depend from claim 1, directly or indirectly, and therefore include all of its limitations. Accordingly, these claims are also not obvious in view of the cited combination for at least the same reasons that claim 1 is not obvious.

Claims 21-30:

Claim 21 is also directed to a method of manufacturing an introducer sheath. The steps as recited in this claim are generally illustrated in the figures of the present application, such as the sequences shown in Figs. 6 and 7. As stated above, the cited art does not teach or suggest the feature of combining first and second sleeves having respective striped extrusions as described over an inner liner and a coil, and melting the first and second sleeves in a heat shrink enclosure to form an outer tube. In this manner, a sheath is obtained having the desirable features of 1) a thin wall; 2) enhanced kink resistance provided by the radially inner coil; and 3) enhanced torqueability provided by the braid-like arrangement of the first and second striped extrusions. Such a

sheath is clearly not derivable from the prior art methods referenced by the Examiner in the citations, either individually or in combination.

The Examiner has acknowledged that Hoste does not explicitly teach the "positioning" steps of the claimed method that involve the arrangement of the two polymeric sleeves. Accordingly, Hoste also cannot teach or suggest the "heating" step that causes the first and second "positioned" sleeves to melt together to form the *outer* tubular layer.

Van Muiden was said to teach a two layer polymer sleeve for a catheter including striped helical patterns for defining a braid-like configuration. However, as stated above, Van Muiden does not teach or suggest the manner of achieving the braid-like action in a thin-walled sheath by melting the two extruded layers together in a heat shrink material. Appellant respectfully submits that the combined disclosures of the cited references fall well short of teaching or suggesting the claimed method. There is no basis, other than hindsight, for combining these two references in a manner to construct a dual reinforcement sheath, since no such teaching or suggestion is provided in either reference. This is particularly significant when, as here, both references acknowledge the problem of excessive wall thickness, and yet fail to teach or suggest the manner of addressing this problem as claimed herein. Further, even when impermissible hindsight to combine is utilized, the combination still falls short of the features of the claimed method.

For at least the foregoing reasons, as well as the reasons discussed above with reference to claim 1, Appellant submits that claim 21 is not obvious in view of the cited combination of references. Claims 22-30 depend from claim 21, directly or indirectly, and therefore include all of its limitations. Accordingly, these claims are also not obvious in view of the cited combination for at least the same reasons that claim 21 is not obvious.

ISSUE 2.

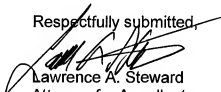
Are claims 31 and 32 unpatentable under 35 USC 103(a) over Hoste in view of van Muiden, as applied to claims 21 and 27, and further in view of Garabedian?

Garabedian was cited for teaching the feature of utilizing radiopaque material in the formation of a catheter. Each of claims 31 and 32 depends, indirectly, from claim 21, and therefore, includes all of its limitations. Garabedian does not teach or suggest the features described above in the discussion of claim 21 that are lacking when the Hoste/van Muiden combination is made. Accordingly, claims 31 and 32 are also not obvious for at least the same reasons that claim 21 is not obvious.

Conclusion

Based upon the foregoing, Appellant respectfully submits that the Examiner's rejections of claims 1, 2, 4, 6-8, 10, and 21-33 are erroneous and not consistent with the applicable law. Accordingly, Appellant respectfully requests that the rejections be reversed by this Board.

Respectfully submitted,



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VIII. CLAIMS APPENDIX

1. A method of manufacturing an introducer sheath, comprising:

positioning a coil over a mandrel;

positioning a first polymeric sleeve over the coil and the mandrel, the first polymeric sleeve comprising a first striped extrusion arranged in a generally helical pattern along an outer surface of the first sleeve;

positioning a second polymeric sleeve over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve, the second striped extrusion having a pitch extending in a generally opposite direction from a pitch of the first striped extrusion;

positioning a heat shrink tube over an assembly comprising the mandrel, coil, and first and second sleeves; and

heating the assembly to a temperature sufficient to cause the heat shrink material to shrink, such that the first and second polymeric sleeves melt together to form a tubular polymeric sheath body enveloping said coil, said second striped extrusion being superposed over said first striped extrusion in said sheath body to define a generally braid-like configuration therein, said braid-like configuration disposed radially outwardly from said coil.

2. The method of claim 1, wherein said first striped extrusion comprises a plurality of extruded first stripes formed in said first polymeric sleeve, each said first stripe spaced from an adjoining stripe and arranged in said generally helical pattern, and said second striped extrusion comprises a plurality of extruded second stripes formed in said second polymeric sleeve, each said second stripe spaced from an adjoining stripe and arranged in said generally helical pattern.

3. (Canceled)

4. The method of claim 1, wherein the second striped extrusion is provided along an inner surface of the second polymeric sleeve.

5. (Canceled)

6. The method of claim 1, wherein the first polymeric sleeve is co-extruded with the first striped extrusion, and the second polymeric sleeve is co-extruded with the second striped extrusion.

7. The method of claim 1, comprising positioning an inner liner over the mandrel intermediate the mandrel and the first polymeric sleeve.

8. The method of claim 7, wherein the sheath body is bonded to the inner liner between the coil turns by the heating.

9. (Canceled)

10. The method of claim 1, wherein at least one of said polymeric sleeves comprises at least two sleeve segments along a length of said sleeve, said segments axially aligned along said sleeve length such that a more proximal segment is of higher durometer and a more distal segment is of lower durometer.

11-20. (Canceled)

21. A method of manufacturing an introducer sheath, comprising:
positioning an inner liner over a mandrel;

positioning a coil over the inner liner, the coil having a plurality of coil turns;

positioning a first polymeric sleeve over the coil, the first polymeric sleeve comprising a first striped extrusion arranged in a generally helical pattern along the first sleeve;

positioning a second polymeric sleeve over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve, the second striped extrusion having a pitch generally opposite a pitch of the first striped extrusion, said second sleeve being aligned over said first sleeve such that upon a melting of said sleeves said second striped extrusion is superposed over said first striped extrusion and a generally braid-like configuration is defined thereby;

positioning a heat shrink material over an assembly comprising the mandrel, inner liner, coil, and first and second sleeves; and

heating the assembly to a temperature sufficient to cause said heat shrink material to shrink, said heating further causing said first and second sleeves to melt together to form an outer tubular layer and to define said generally braid-like configuration therein, wherein said heat shrink material causes said outer tubular layer to bond to said inner liner through said coil turns.

22. The method of claim 21, further comprising the steps of removing said mandrel and heat shrink material.

23. The method of claim 21, wherein the first striped extrusion is provided along an outer surface of the first polymeric sleeve, and the second striped extrusion is provided along an inner surface of the second polymeric sleeve.

24. The method of claim 21, wherein said first striped extrusion comprises a plurality of extruded first stripes formed in said first polymeric sleeve, each said first stripe spaced from an adjoining stripe and arranged in said generally helical pattern, and said second striped extrusion comprises a plurality of extruded second stripes formed in said second polymeric sleeve, each said second stripe spaced from an adjoining stripe and arranged in said generally helical pattern.

25. The method of claim 21, wherein the first polymeric sleeve is co-extruded with the first striped extrusion, and the second polymeric sleeve is co-extruded with the second striped extrusion.

26. The method of claim 21, wherein at least one of said polymeric sleeves comprises at least two sleeve segments, said segments comprising a proximal segment of a higher durometer and a distal segment of a lower durometer.

27. The method of claim 21, wherein each of said polymeric sleeves comprises at least two sleeve segments, said segments comprising a proximal segment of a higher durometer and a distal segment of a lower durometer.

28. The method of claim 21, wherein said sleeves are formed from a polyamide material.

29. The method of claim 28, wherein at least one of said first and second striped extrusions is formed from a polyamide material having a higher durometer than a durometer of said sleeves.

30. The method of claim 21, further including the step of forming at least one of said sleeves comprising said striped extrusion by a stripe extrusion process.

31. The method of claim 27, wherein at least one of said polymeric sleeves includes a radiopaque sleeve distal of said distal segment.

32. The method of claim 31, wherein said radiopaque sleeve has a lower durometer than said distal segment.

33. The method of claim 1, wherein each of said first and second sleeves has a pre-heated wall thickness of from about 0.005 to 0.010 inch [0.127 to 0.254 mm].

IX. EVIDENCE APPENDIX

None.

X. RELATED DECISIONS APPENDIX

None.